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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/751,271 | 12/28/2000 | Clifton A. Alferness | 1931-1 | 8995 |

996 7590 03/11/2004

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| EXAMINER | |
|---|---|
| ODLAND, KATHRYN P | |
| **ART UNIT** | **PAPER NUMBER** |
| 3743 | |

DATE MAILED: 03/11/2004

13

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. 09/751,271 | Applicant(s) ALFERNESS ET AL. |
|---|---|---|
| | Examiner Kathryn Odland | Art Unit 3743 |

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *12 January 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9, 10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Response to Amendment*

This is a response to the amendment dated January 12, 2004. Claims 1-50 are pending. The amendments to the drawings, specification and title are acknowledged.

### *Response to Arguments*

1. Applicant's arguments filed January 12, 2004 have been fully considered but they are not persuasive.

Applicant's argues, "There is no specific application of Houser et al. to the claims seeking to demonstrate correspondence of described and illustrated structure to the claimed elements. Rather, the Office Action repeats claim recitation back and then makes reference to extensive portions of Houser et al. as demonstrating claim correspondence." The examiner attempted to thoroughly address all claimed subject matter via clearly indicated corresponding elements and directing applicant to critical text. Further, it is not believed that the Houser et al. reference in its entirety is an extensive amount of text. Moreover, applicant was channeled to specific passages that again the examiner did not considered extensive.

Applicant further argues, Houser et al. do not mention the coronary sinus. However, applicant is directed to section [0138] which recites, "Alternatively, a catheter may be inserted into the coronary vasculature, particularly the **coronary sinus**, via the aorta to deliver the clip." Further, section [0134] recites, "Delivering and placing the clip over the desired tissue, valve, or opening may be accomplished by several different methods." The method via the coronary sinus is clearly discussed in section [0138].

The examiner asserts this recitation is quite explicit and did not feel further explanation was necessary.

Applicant argues, Houser et al. do not show, describe, or suggest a releasable coupling. However, given a reasonably broad interpretation of a 'releasable coupling', Houser et al. clearly demonstrate releasing the clip from an introducer where the plunger assembly can be considered a releasable coupling, for when the plunger forces the clip out of the housing they are released from contact. Moreover, the discussion, "The releasable coupling between the device and the introducer allows the device to deliver therapy while attached to the introducer. If therapy is successful, the device may then be decoupled from the introducer and left in the coronary sinus. However, if it necessary or desirable to remove the device after the mitral therapy, the device may be readily removed as it is still coupled to the introducer." do not appear to be relevant or claim limitations.

Moreover, the examiner asserts Houser et al. do not point away from the invention. Further, applicant states, "Houser et al. does not even mention the coronary sinus as an implantation site." The scope of this phrase is not clear. Applicant's method claims are directed to advancing a constrictive device into the coronary sinus to partially encircle the mitral valve. It seems the implantation site is the mitral valve not the coronary sinus. Houser et al. clearly recite inserting a catheter into the coronary sinus and placing a clip/constrictive device to constrict the mitral valve.

The scope of the recitation, "Nothing remains in the coronary sinus to deliver therapy to the mitral valve." is also not clear. The clip itself can be considered therapy to the mitral valve and applicant's claim language provides no other requirement.

Applicant is also reminded that function language does not hold patentable weight in apparatus claims. Thus, aside from the method claims, the functional language such as the necessity for implantation via the coronary sinus is not required and not given patentable weight. Applicant has failed to define structural features that define over Houser et al.

2. Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

The rejection is reiterated below.

### *Claim Rejections - 35 USC § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-7, 9-17, 19, 25-28, and 31-45 are rejected under 35 U.S.C. 102(e) as being anticipated by Houser et al. in US 2002/0035361.

Regarding claim 1, Houser et al. disclose: a device (such as 406, 410, 414, etc) for effecting the condition of a mitral valve (such as seen as 402) annulus of a heart having a resilient member having a cross sectional dimension for being received within the coronary sinus (such as labeled 198) of the heart and having a longitudinal dimension having an arched configuration for partially encircling the mitral valve and exerting an inward pressure on the mitral valve when within the coronary sinus adjacent the mitral valve for constricting the mitral valve annulus, as recited in section [0014], [0121]-[0143], claims 1-97 and seen in figures 27A-43B

Regarding claims 2, 35 and 42, Houser et al. disclose: a resilient member that has a distal end and a proximal end, and wherein the distal end and proximal end define an included angle of at least 180.degree, as seen in figures 27A-43B.

Regarding claims 3, 36, and 43, Houser et al. disclose: a resilient member that has a distal end and a proximal end and wherein the resilient member longitudinal dimension is of a length to cause the proximal end of the resilient member to be proximal to the ostium of the coronary sinus, as seen in figures 27A-43B.

Regarding claims 4 and 44, Houser et al. disclose: a resilient member that includes at least one fixation element, as recited, for example in sections [0123]-[0126].

Regarding claims 5, 37 and 45, Houser et al. disclose: at least one fixation element that is at a proximal end of the resilient member, as recited, for example in sections [0123]-[0126] and seen in figures 27A-43B.

Regarding claim 6, Houser et al. disclose: at least one fixation element that is a plurality of teeth formed in the resilient member, as recited in sections [0117], [0123]-[0126] and seen in figures 27A-43B.

Regarding claim 7, Houser et al. disclose: at least one fixation element that is material mesh, (such as the grids disclosed) as recited in sections [0115]-[0129], for example.

Regarding claim 9, Houser et al. disclose: a resilient member is formed of an alloy including at least nickel and titanium, as recited in section [0115] and [0127].

Regarding claim 10, Houser et al. disclose: a mitral valve annulus constricting device having a generally C-shaped clip member formed of resilient material for exerting a substantially radially inward force on the mitral valve annulus when placed in the coronary sinus of a heart about and adjacent to the mitral valve, as recited in section [0014], [0121]-[0143], claims 1-97 and seen in figures 27A-43B.

Regarding claim 11, Houser et al. disclose: a mitral valve therapy system having: a resilient member having a cross sectional dimension for being received within the coronary sinus of a heart and having a longitudinal dimension having an arched configuration for partially encircling the mitral valve of the heart and exerting a substantially radially inward compressive force on the mitral valve annulus of the heart when placed within the coronary sinus adjacent the mitral valve, the resilient member having a proximal end including a coupling mechanism (such as 450 with 448); and, an elongated introducer (such as 436) formed of flexible material and having a distal end including a coupling mechanism for being releasably coupled to the resilient member coupling member for guiding the resilient member into the coronary sinus of the heart and being detached from the resilient member once the resilient member is placed within the coronary sinus to permit the introducer to be removed from the heart while leaving the resilient member positioned within the coronary sinus, as recited in section [0014], [0121]-[0143], claims 1-97 and seen in figures 27A-43B.

Regarding claim 12, Houser et al. disclose: a resilient member that has a distal end opposite the proximal end, and wherein the distal end and proximal end define an included angle of at least 180.degree, as seen in figures 27A-43B.

Regarding claim 13, Houser et al. disclose: a resilient member longitudinal dimension that is of a length to cause the proximal end of the resilient member to be proximal to the ostium of the coronary sinus, as seen in figures 27A-43B.

Regarding claim 14, Houser et al. disclose: s resilient member that includes at least one fixation element, as recited in sections [0117]-[0129].

Regarding claim 15, Houser et al. disclose: at least one fixation element that is at the proximal end of the resilient member, as recited in sections [0117]-[0129] and seen in figures 27A-43B.

Regarding claim 16, Houser et al. disclose: at least one fixation element that is a plurality of teeth formed in the resilient member, as recited in sections [0117]-[0129].

Regarding claim 17, Houser et al. disclose: at least one fixation element that is material mesh (such as the grid), as stated in sections [0117]-[0129].

Regarding claim 19, Houser et al. disclose: a resilient member that is formed of an alloy including at least nickel and titanium, as recited in sections [0115] and [0127].

Regarding claim 25, Houser et al. disclose: a method of treating dilated cardiomyopathy of a heart of a patient, the method including the steps of: providing a constriction device

formed of resilient material having an unstressed C-shape configuration with an effective radius less than a dilated mitral valve annulus radius and a cross sectional dimension for being received within the coronary sinus of the heart; and advancing the constriction device into the coronary sinus of the heart until the constriction device at least partially encircles the mitral value of the heart, as recited in section [0014], [0121]-[0143], claims 1-97 and seen in figures 27A-43B.

Regarding claim 26, Houser et al. disclose: an advancing step that includes releasably coupling the constriction device to an elongated flexible introducer (such as 436) and moving the constriction device into the coronary sinus with the introducer, as recited in section [0014], [0121]-[0143], claims 1-97 and seen in figures 27A-43B.

Regarding claim 27, Houser et al. disclose: releasing the introducer from the constriction device when the constriction device at least partially encircles the mitral valve and removing the introducer from the patient, as recited in section [0014], [0121]-[0143], claims 1-97 and seen in figures 27A-43B.

Regarding claim 31, Houser et al. disclose: a mitral valve annulus constricting device having a generally C-shaped clip member formed of resilient material for exerting a substantially radially compressive force on the mitral valve annulus when placed adjacent to the mitral valve, as recited in section [0014], [0121]-[0143], claims 1-97 and seen in figures 27A-43B.

Regarding claim 32, Houser et al. disclose: a device that provides therapy to a mitral valve annulus of a heart where the device is dimensioned for placement in the coronary sinus of the heart adjacent to the mitral valve annulus and that effects the geometry of the mitral valve annulus to provide therapy to the mitral valve annulus, the device having a coupler that releasably couples the device to an introducer that places the device within the coronary sinus, the device being configured to provide therapy to the mitral valve annulus while coupled to the introducer, as recited in sections such as [0071]-[0089] and seen in figures such as 5A.

Regarding claim 33, Houser et al. disclose: a system for providing therapy to a mitral valve annulus of the heart having a device dimensioned for placement in the coronary sinus of the heart adjacent to the mitral valve annulus of the heart, the device effecting the shape of the mitral valve annulus to provide therapy to the mitral valve annulus, the device including a coupler that provided releasable coupling to the device; and an introducer configured to be releasably coupled to the device coupler and that places the device in the coronary sinus adjacent to the mitral valve annulus, where the device is configured to provide therapy to the mitral valve annulus while coupled to the introducer, as discussed throughout the specification and claims.

Regarding claim 34, Houser et al. disclose: a device for changing the condition of the mitral valve annulus of the heart having a resilient member having a cross sectional

dimension for being received within the coronary sinus of the heart and having a longitudinal dimension having a preformed arched configuration for partially encircling the mitral valve and exerting inward pressure on the mitral valve when within the coronary sinus adjacent the mitral valve for constricting the mitral valve; and at least one fixation element, as recited in section [0014], [0121]-[0143], claims 1-97 and seen in figures 27A-43B.

Regarding claim 38, Houser et al. disclose a coupling mechanism adapted to couple with an introducer, as recited in section [0014], [0121]-[0143], claims 1-97 and seen in figures 27A-43B.

Regarding claim 39, Houser et al. disclose means for adjusting the position of the device, as recited in section [0014], [0121]-[0143], claims 1-97 and seen in figures 27A-43B.

Regarding claim 40, Houser et al. disclose means for removing the device from the heart, as recited in section [0014], [0121]-[0143], claims 1-97 and seen in figures 27A-43B.

Regarding claim 41, Houser et al. disclose: a mitral valve therapy system having a resilient member having a cross sectional dimension for being received within the coronary sinus of a heart and having a longitudinal dimension having an arched

configuration for partially encircling the mitral valve of the heart and exerting a substantially radially inward compressive force on the mitral valve annulus of the heart when placed within the coronary sinus adjacent the mitral valve, the resilient member having a proximal end including a coupling mechanism; and an elongated introducer (such as 436) formed of flexible material and having a distal end including a coupling mechanism (such as 448 with 450) for being releasably coupled to the resilient member coupling member for guiding the resilient member into the coronary sinus of the heart and being detached from the resilient member once the resilient member is placed within the coronary sinus to permit the introducer to be removed from the heart while leaving the resilient member positioned within the coronary sinus, as recited in section [0014], [0121]-[0143], claims 1-97 and seen in figures 27A-43B.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 8, 18, 20-24, 29-30, and 46-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houser et al. in US 2002/0035361.

Houser et al. disclose the invention with the exception of:

- A material mesh that is a polyester mesh (claims 8 and 18)
- An introducer that is formed of stainless steel (claim 20)

- An elongated cylindrical sheath dimension for receiving the resilient member and the introducer, the sheath being flexible for advancement into the coronary sinus and guiding the resilient member into the coronary sinus (claim 21)
- A sheath that has a distal end and wherein the resilient member coupling mechanism and introducer coupling mechanism are releasable when the distal end of the sheath is proximal to the introducer coupling mechanism (claim 22)
- A sheath that is formed of polyester (claim 23)
- A resilient member and introducer that are rotatable relative to one another for causing the introducer coupling mechanism and resilient member coupling mechanism to release (claim 24)
- Placing a cylindrical sheath within the coronary sinus of the heart of the patient, the sheath having a cross sectional dimension for receiving the introducer and constriction device, and wherein the advancing step includes the step of guiding the introducer and constriction device into the coronary sinus within the sheath (claim 28)
- Releasing the introducer from the constriction device when the constriction device at least partially encircles the mitral valve and removing the introducer and sheath from the patient (claim 29)
- Retracting the sheath until the sheath is proximal to the constriction device prior to releasing the introducer from the constriction device (claim 30)
- An elongated cylindrical sheath dimensioned for receiving the resilient member and the introducer, the sheath being dimensioned for receiving the resilient

member and the introducer where the sheath is flexible for advancement into the coronary sinus and guiding the resilient member into the coronary sinus (claim 46)

- A sheath that has a distal end and wherein the resilient member coupling mechanism and introducer coupling mechanism are releasable when the distal end of the sheath is proximal to the introducer coupling mechanism (claim 47)
- A resilient member and introducer that are rotatable relative to one another for causing that introducer coupling mechanism and the resilient member coupling mechanism to release (claim 48)
- A resilient member that has mean for adjusting the position of the resilient member (claim 49)
- A resilient member that has means for removing the resilient member from the heart (claim 50)

On the other hand, it would be obvious to one with ordinary skill in the art to modify the invention of Houser et al. to include a material mesh that is a polyester mesh for the purpose of cushioning.

Further, the specification of the current application does not demonstrate the criticality for having an introducer that is formed of stainless steel. Further, it would be obvious to one with ordinary skill in the art to assure the introducer is formed of stainless steel for it is a well-known material for introducers.

Moreover, Houser et al. state that there are numerous ways to implant the mitral valve device. Therefore, it would be obvious to one with ordinary skill in the art to modify the deployment technique of Houser et al. to include: an elongated cylindrical sheath dimension for receiving the resilient member and the introducer, the sheath being flexible for advancement into the coronary sinus and guiding the resilient member into the coronary sinus; a sheath that has a distal end and wherein the resilient member coupling mechanism and introducer coupling mechanism are releasable when the distal end of the sheath is proximal to the introducer coupling mechanism; a sheath that is formed of polyester; a resilient member and introducer that are rotatable relative to one another for causing the introducer coupling mechanism and resilient member coupling mechanism to release; placing a cylindrical sheath within the coronary sinus of the heart of the patient, the sheath having a cross sectional dimension for receiving the introducer and constriction device, and wherein the advancing step includes the step of guiding the introducer and constriction device into the coronary sinus within the sheath; releasing the introducer from the constriction device when the constriction device at least partially encircles the mitral valve and removing the introducer and sheath from the patient; retracting the sheath until the sheath is proximal to the constriction device prior to releasing the introducer from the constriction device; an elongated cylindrical sheath dimensioned for receiving the resilient member and the introducer, the sheath being dimensioned for receiving the resilient member and the introducer where the sheath is flexible for advancement into the coronary sinus and guiding the resilient member

into the coronary sinus; a sheath that has a distal end and wherein the resilient member coupling mechanism and introducer coupling mechanism are releasable when the distal end of the sheath is proximal to the introducer coupling mechanism; a resilient member and introducer that are rotatable relative to one another for causing that introducer coupling mechanism and the resilient member coupling mechanism to release; a resilient member that has mean for adjusting the position of the resilient member; and a resilient member that has means for removing the resilient member from the heart for the purpose of a more controlled delivery.

***Conclusion***

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KO

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